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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/194,053 11/23/98 CHOKRI

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EXAMINER

VANDER VEGT, F

ART UNIT

PAPER NUMBER

1644

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DATE MAILED:

01/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/194,053

Applicant(s)
Chokri et al

Examiner
F. Pierre VanderVegt

Group Art Unit
1644



☒ Responsive to communication(s) filed on Oct 15, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 44-66, 75, 76, 80-84, and 86 is/are pending in the application.

Of the above, claim(s) 82-84 and 86 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 44-66, 75, 76, 80, and 81 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3, 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a rule 371 continuation of PCT/EP97/02703.

Claims 67-74, 77-79 and 85 have been canceled. New claim 86 has been added.

Claims 44-66, 75, 76, 80-84 and 86 are currently pending in this application.

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Election/Restriction

1. Applicant's election with traverse of Group I, claims 44-66 and 75-76 and 80-81, in Paper No. 6, filed October 15, 1999, is acknowledged. The traversal is on the ground(s) that new claim 86 bridges Groups I and V, thereby necessitating a search of both groups. This is not found
10 persuasive because while claim 86 does recite the use of the product of Group I, it is dependent upon the broader method of claim 82, which encompasses embodiments not related to the product of Group I and therefore does not fall within the inventive concept of the product of Group I. Further, it is maintained that the product of Group I is obtainable by means other than the method of Group II, which is a limiting condition upon Group V.

15 The requirement is still deemed proper and is therefore made FINAL.

2. Claims 82-84 and 86 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 6.

20 Claims 44-66 and 75-76 and 80-81 are the subject of examination in the present office action.

Claim Rejections - 35 U.S.C. § 112

3. Claims 48, 52, 56, 57, 59, 60, 62-66, 75, 76, 80 and 81 are rejected under 35 U.S.C. 112,
25 first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to populations of monocyte-derived antigen presenting cells (MD-APCs) identified on the basis of the presence of particular cell surface antigens based upon mean intensity. The specification is not enabling for the isolation of the claimed cells for a multitude of reasons. First of all, the specification and claims fail to identify the fluorochrome used and the
5 excitation wavelength at which fluorescence is detected. It is well established in the art that different fluorochromes, such as fluorescein, phycoerythrin, and TEXAS RED, have different intensities and optimally fluoresce at different wavelengths as measured in nanometers. Further, the specification does not identify the nature of the units used for the measurement of mean intensity fluorescence. Second, the specification and claims fail to identify the staining reagent
10 adequately. Are the fluorochrome molecules attached to antigens specifically bound by the specified surface determinants or are they attached to antibodies specific for said surface determinants? Are the fluorochromes covalently bound to the antibody or antigen or is binding effected by indirect means, such as biotin-avidin affinity? Are the antibodies full length, Fab or F(ab')₂ fragments? In the absence of specifying standardized commercially available reagents,
15 what is the molar ratio of the fluorochrome to the antigen/antibody/avidin? What staining conditions (temperature, light, time) are used? All of these variables would be recognized by one skilled in the art to be factors which directly influence mean intensity fluorescence. The specification states, for example, that FITC and PE labeled antibodies were used in working examples (page 16, for example), however fails to address any of the other variables inherent in
20 the procedure of fluorescent staining and detection. In view of the insufficient guidance provided by the instant specification, it would not be possible for the artisan to reasonably predict the conditions needed to adequately identify the cells commensurate in scope with the claims and it would require a level of experimentation on the part of the practitioner which could not be considered routine.

25 In view of the nature of the invention, quantity of experimentation necessary, the level of the skilled artisan, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

4. Claims 47, 48, 52-54, 56, 57, 59, 60, 62-66, 75, 76, 80 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5 Claim 47 recites the limitation "macrophages" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim. Base claim 44 recites only monocyte-derived antigen presenting cells.

10 Claims 48, 52, 56, 57, 59, 62 and 63 each recite "mean intensity" of a given range without specifying the units of measurement. Said mean intensities are a relative measurement but fail to identify the fluorochrome or to provide information as to whether they refer to a wavelength range within the cells fluoresce, a multiplier versus the intensity of some baseline or control or whether they refer to intensities upon some numerical scale which has been standardized.

Claim Rejections - 35 U.S.C. § 102

15 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

20 (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 44-66, 75, 76, 80 and 81 are rejected under 35 U.S.C. 102(a,e) as being
25 anticipated by U.S. Patent No. 5,804,442 to Romet-Lemonne et al (A on form PTO-892).

30 The '442 patent teaches the isolation of monocyte-derived antigen presenting cells (MD-APCs), including macrophages (see entire document). The '442 patent further teaches that the MD-APCs obtained are suitable for allogeneic lymphoproliferation (column 10, lines 17-26 in particular). Claims 48, 49, 52, 53, 55-57, 59-66, 75, 76, 80 and 81 are included in this ground of rejection because the macrophages isolated by the method of the '442 patent inherently possess

the variously recited cell surface markers recited in the instant claims, some of which serve as developmental or activation markers of macrophages. Claims 48, 52, 56, 57, 59, 62-66, 75, 76, 80 and 81 are further included because the recited mean intensities of the markers are not expressed in units which would allow the practitioner to differentiate the instantly claimed MD-APCs from the wild-type cells isolated by the method of the '442 patent. Claims 45, 47, 58, 61-66, 75, 76, 80 and 81 are included because the property of phagocytosing particulate antigens, such as formalin-fixed yeast, is an inherent property of macrophages which, in their role as antigen-presenting cells, can phagocytose particulate antigens in an antigen-independent manner, process the antigen and present antigenic fragments on their surface in the context of MHC class I and/or MHC class II for the antigen-specific stimulation of cytotoxic or helper T cells, respectively. The prior art teaching anticipates the claimed invention.

Conclusion

6. The form PTO-1449 filed November 15, 1999 has been lined through because it is a duplicate of the citations of the form PTO-1449 filed November 23, 1998. Only the abstract of WO 96/22781 (AL on form PTO-1449) has been considered because it was the only part of the document in English and no certified translation was provided.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and even-numbered Mondays (on

1999 365-day calender) from 7:00 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

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10 F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
January 3, 2000